

NOV 16 2001

510(K) Summary

K 012790

Submitter: Cynosure, Inc.
10 Elizabeth Drive
Chelmsford, MA 01824

Contact: George Cho
Senior Vice President of Medical Technology

Date Summary Prepared: August 16, 2001

Device Trade Name: PhotoGenica ER Laser

Common Name: Medical Laser System

Classification Name: Instrument, surgical, powered, laser
79-GEX
21 CFR 878.48

Equivalent Device: Continuum Biomedical CB Erbium / 2.94TM Er:YAG Laser

Device Description: The PhotoGenica ER Laser consists of three interconnected sections: the power supply, the water cooling system and the optical bench. At 20 pulses per second and a pulse energy of 2 Joules, the average power from the laser is 20 watts.

Intended Use: Skin resurfacing in the treatment of wrinkles.

Comparison: The PhotoGenica ER Laser is substantially equivalent to the Continuum Biomedical CB Erbium / 2.94TM Er:YAG Laser in terms of treatment wavelength, pulse duration, pulse energy, and biological effects.

Nonclinical Performance Data: none

Clinical Performance Data: none

Conclusion: The PhotoGenica ER Laser is another safe and effective way to remove or reduce wrinkles, and to ablate or excise tissue.

Additional Information: None requested at this time



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. George Cho
Senior Vice President
of Medical Technology
Cynosure, Inc.
10 Elizabeth Drive
Chelmsford, Massachusetts 01824

NOV 16 2001

Re: K012790

Trade/Device Name: PhotoGenica ER Laser

Regulation Number: 878.4810

Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology.

Regulatory Class: II

Product Code: GEX

Dated: August 16, 2001

Received: August 20, 2001

Dear Mr. Cho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 16 2001

Page ____ of ____.

510(k) Number (if known): K012790


Device Name: Cynosure PhotoGenica ER Laser

Indications For Use:

The PhotoGenica ER laser is used for skin resurfacing in the treatment of wrinkles and for the incision, excision ablation or vaporization of soft bodily tissues.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012790

Prescription Use ☒

OR

Over-The-Counter Use _____